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Porter et al.

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(54) **TRANSDERMAL INTRAOSSEOUS DEVICE**

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A61F 2/60 (2006.01)
A61F 2/50 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/60*** (2013.01); ***A61F 2/78*** (2013.01); *A61F 2/28* (2013.01); *A61F 2/2814* (2013.01); *A61F 2/30749* (2013.01); *A61F 2002/5083* (2013.01); *A61F 2002/607* (2013.01); *A61F 2002/7887* (2013.01); *A61F 2220/0008* (2013.01); *A61F 2250/006* (2013.01); *A61F 2250/0064* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/2814
See application file for complete search history.

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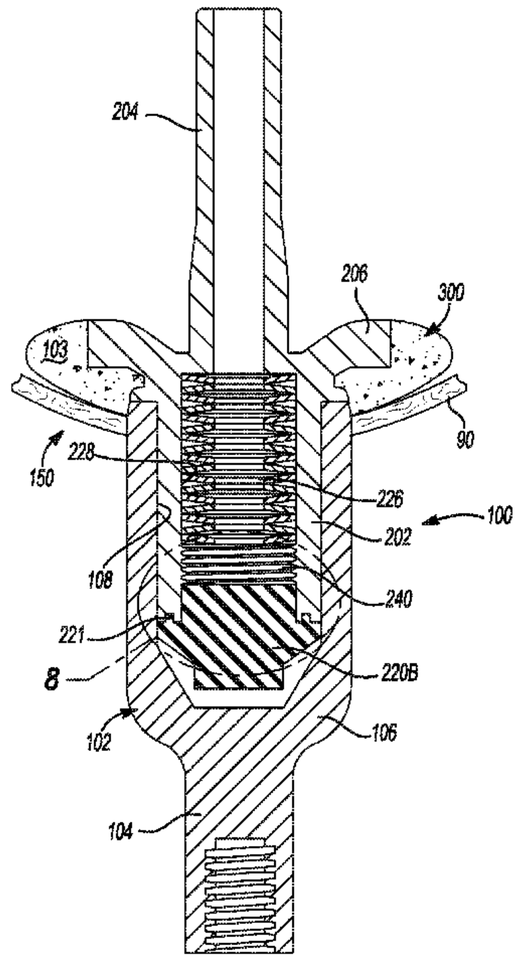
(57) **ABSTRACT**

A transdermal intraosseous device for coupling a bone stump to an external prosthetic device includes a bone fixator, an external connector and a plurality of modular interface components. The bone fixator includes a proximal portion configured for anchoring into the bone stump of the patient and a distal portion including a base collar configured for subcutaneous implantation. The external connector has a distal portion for coupling to the external prosthetic device and a proximal portion for coupling to the distal portion of the bone fixator. Each interface component can be removably coupled to the base collar and has different size and shape to provide a surgeon-selected transition between the prosthetic device and the patient's skin.

16 Claims, 10 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/756,040, filed on Jan. 31, 2013, now Pat. No. 9,023,115.

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A61F 2/30	(2006.01)

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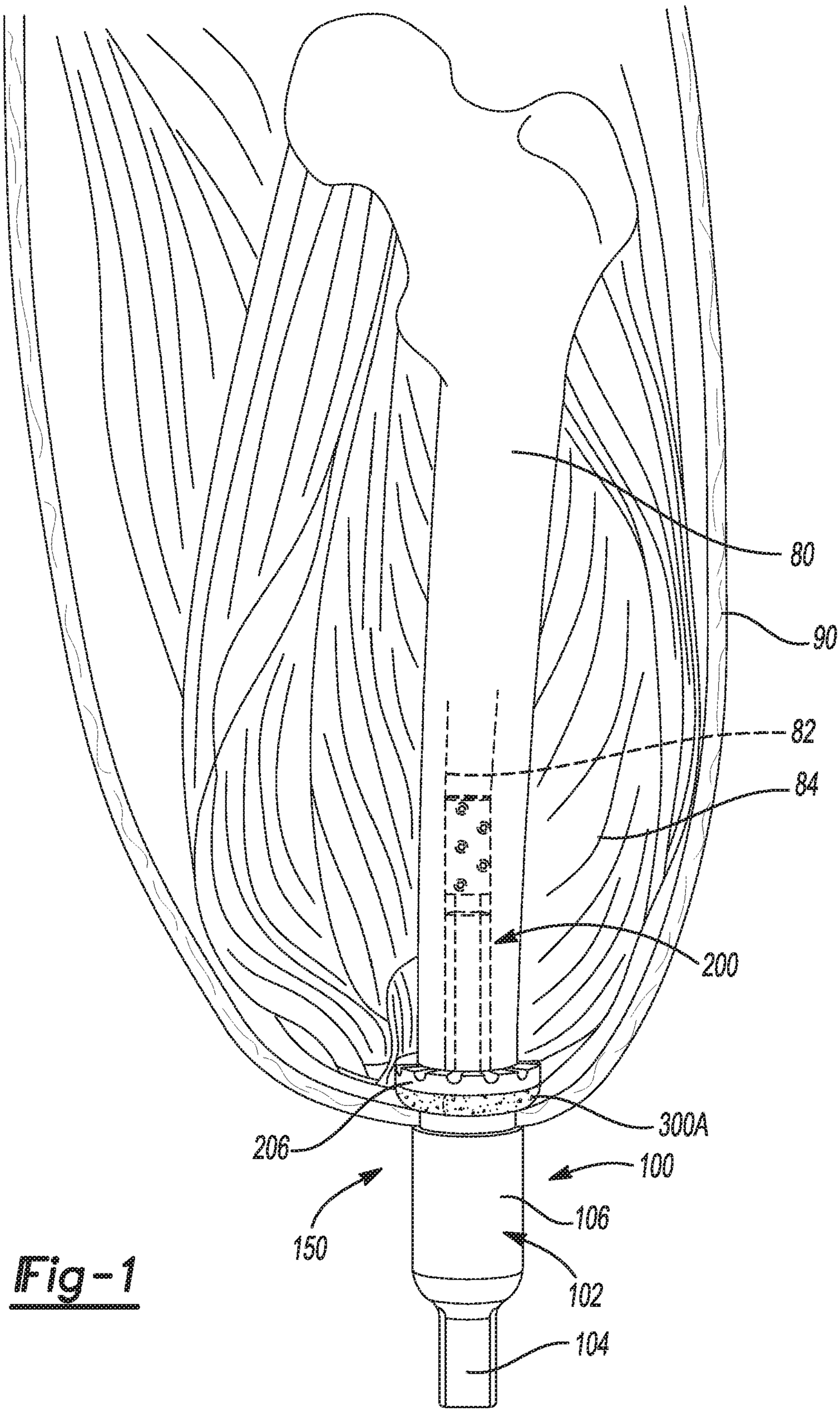
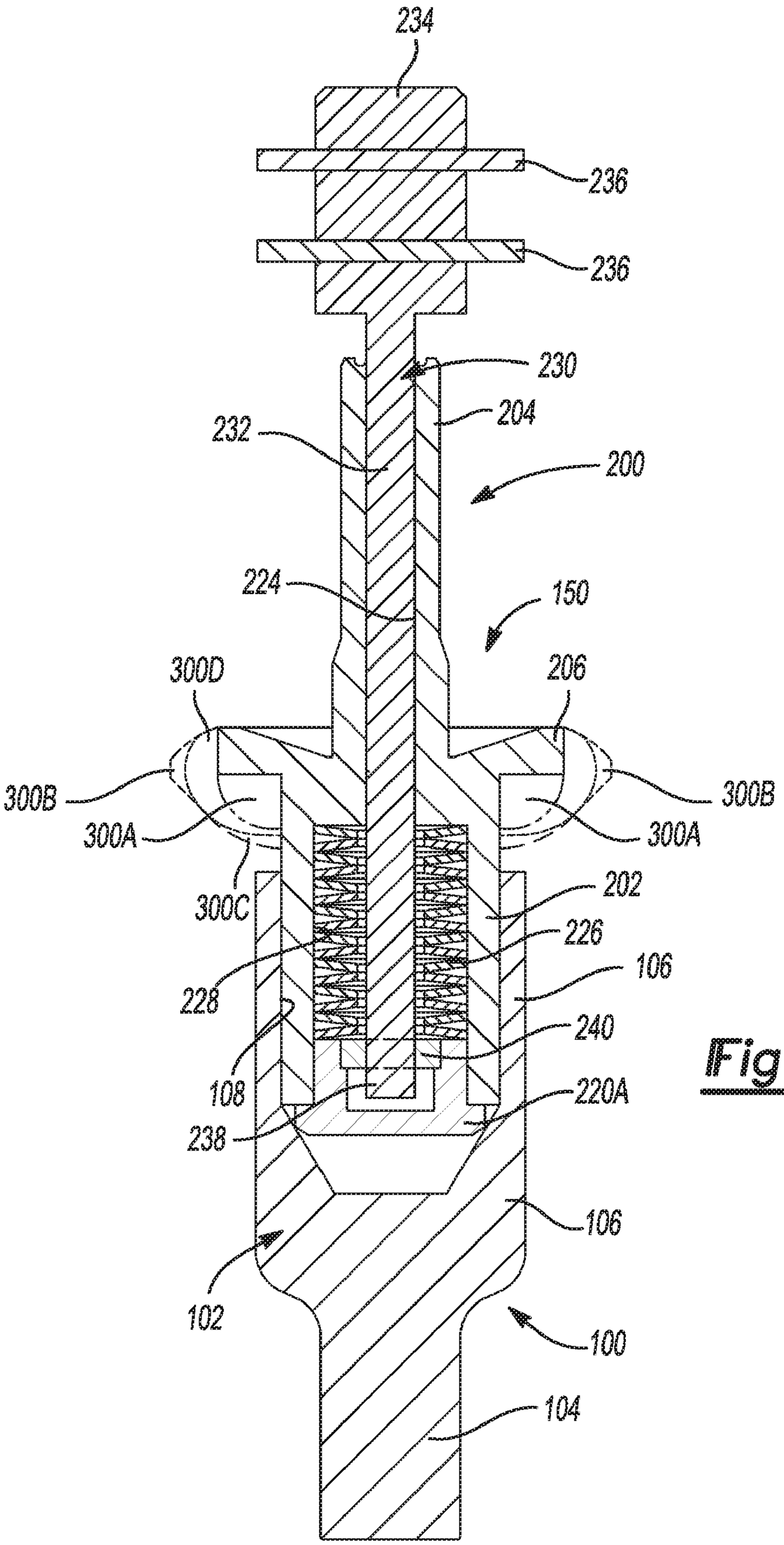


Fig-1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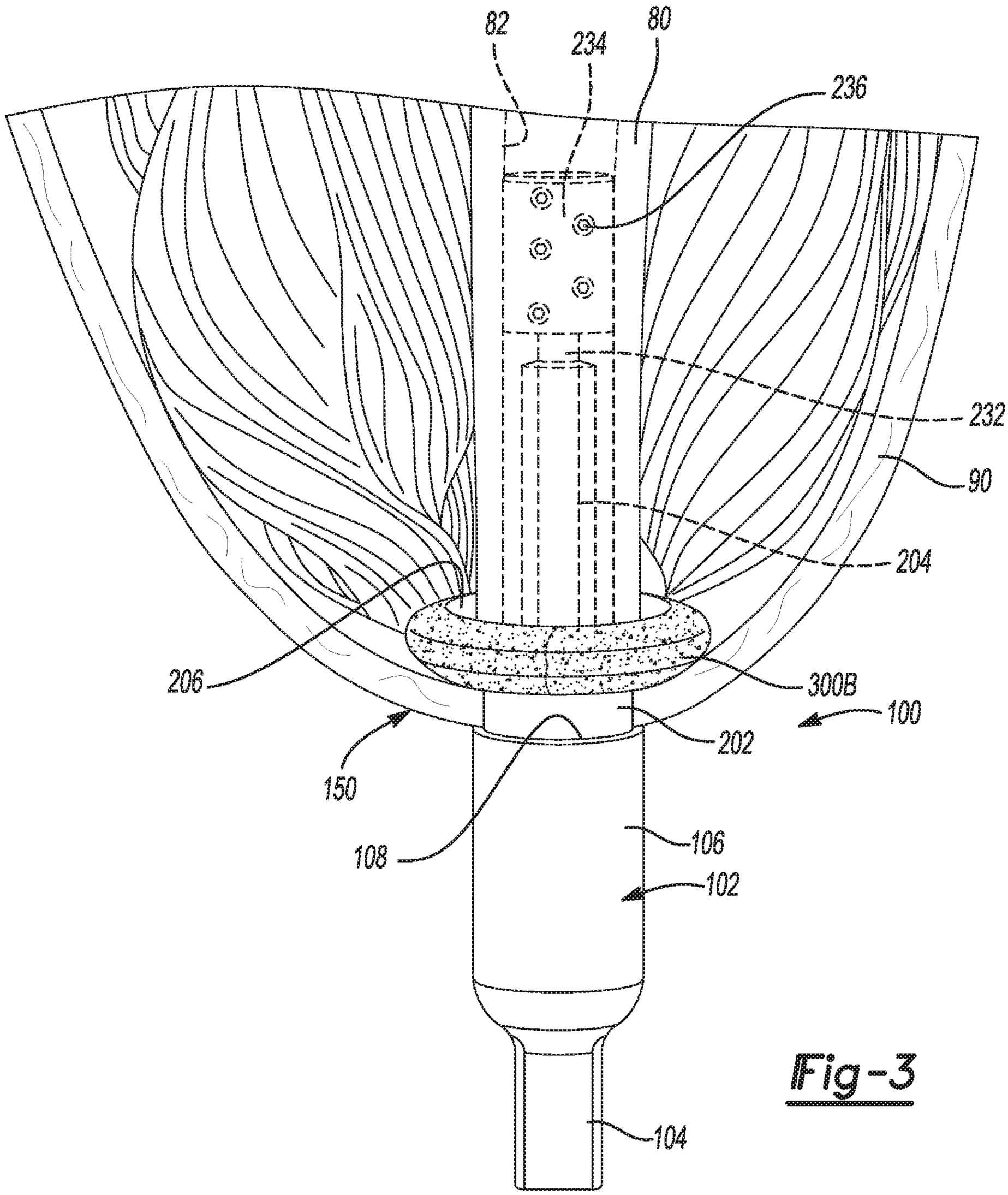
236
236
230
204
232
200
224
150
300D
206
300B
300B
300A
300A
300C
202
226
106
228
240
108
220A
238
106
102
100
104

Fig-2



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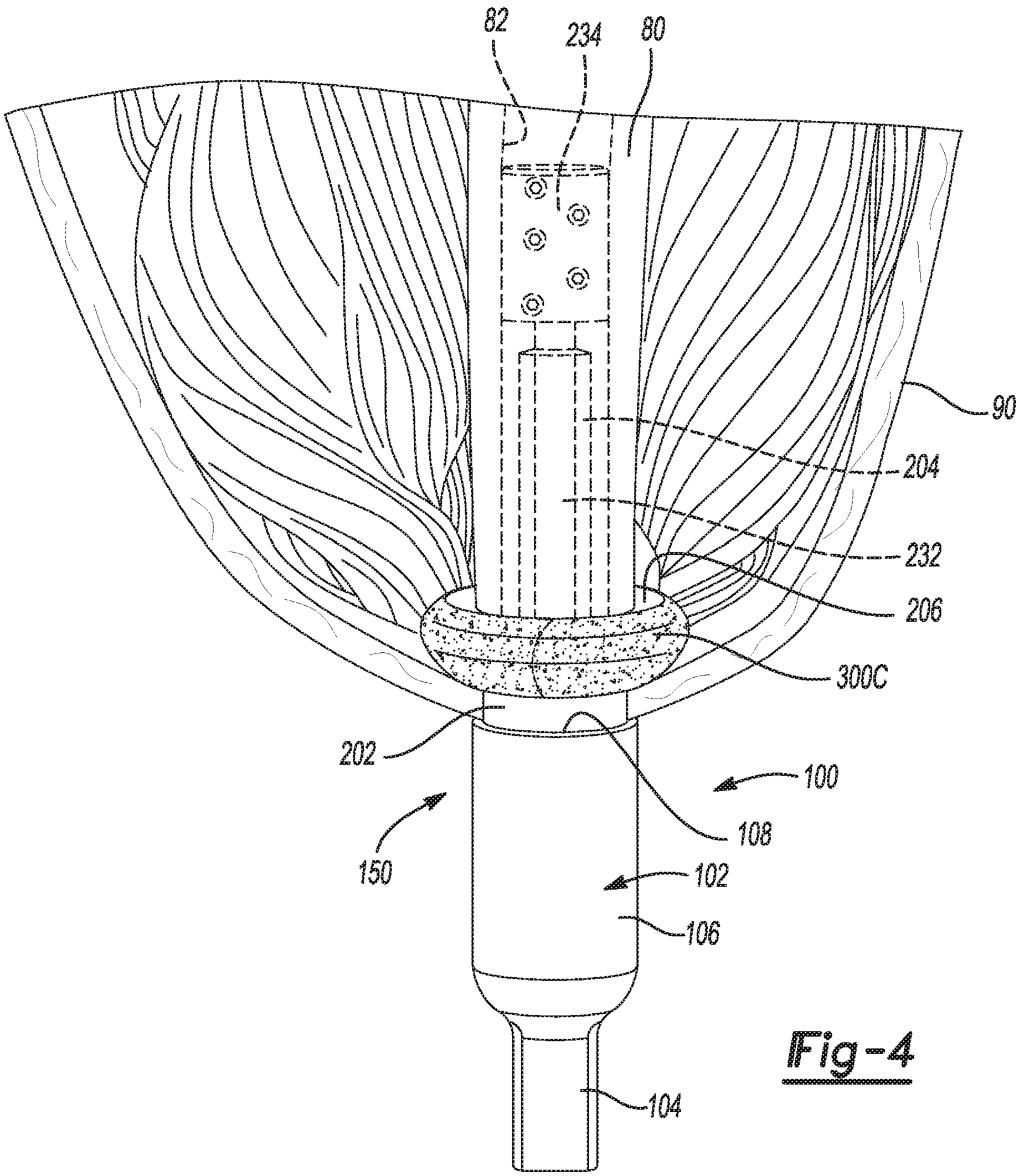
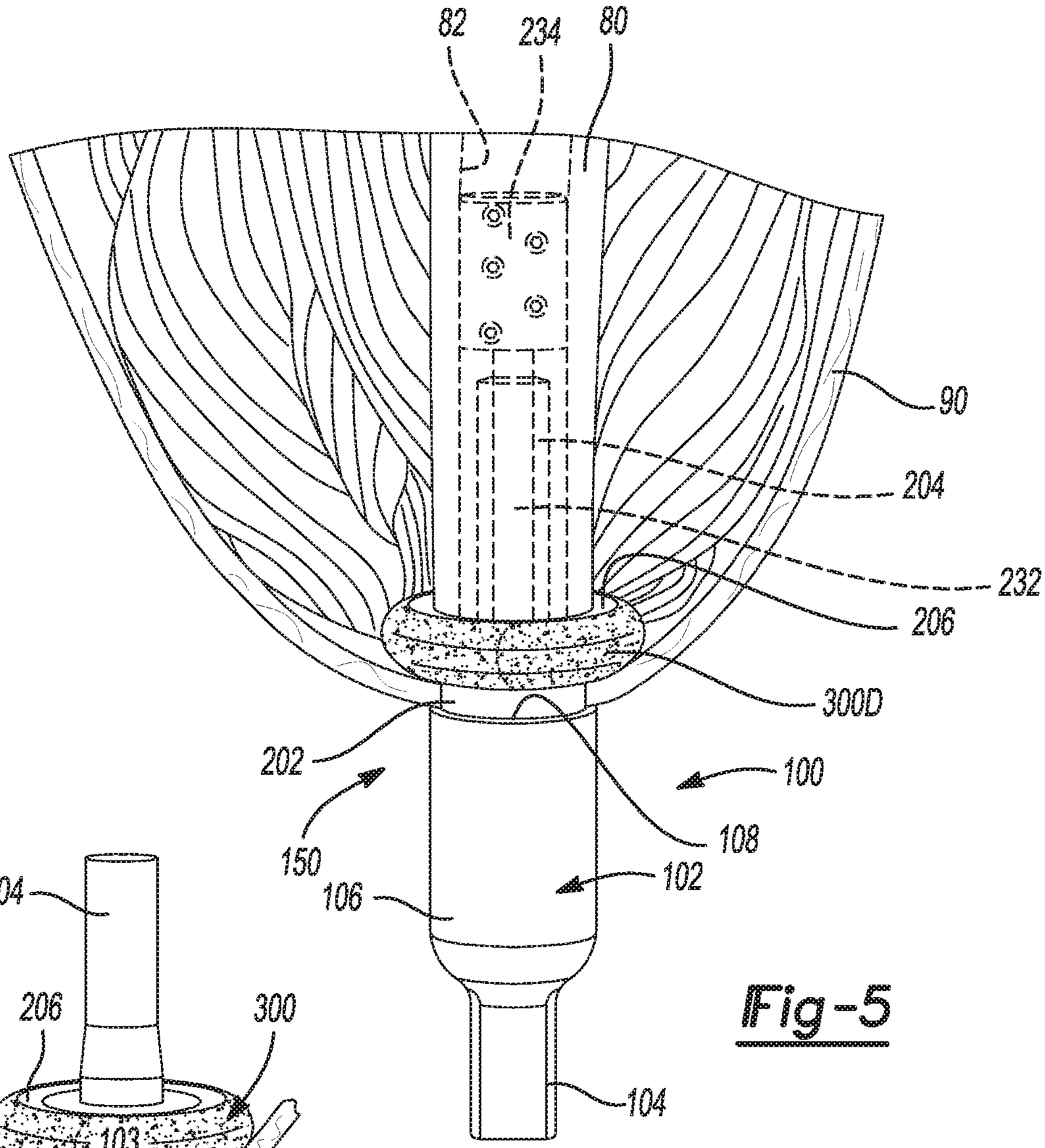


Fig-4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234
80
90
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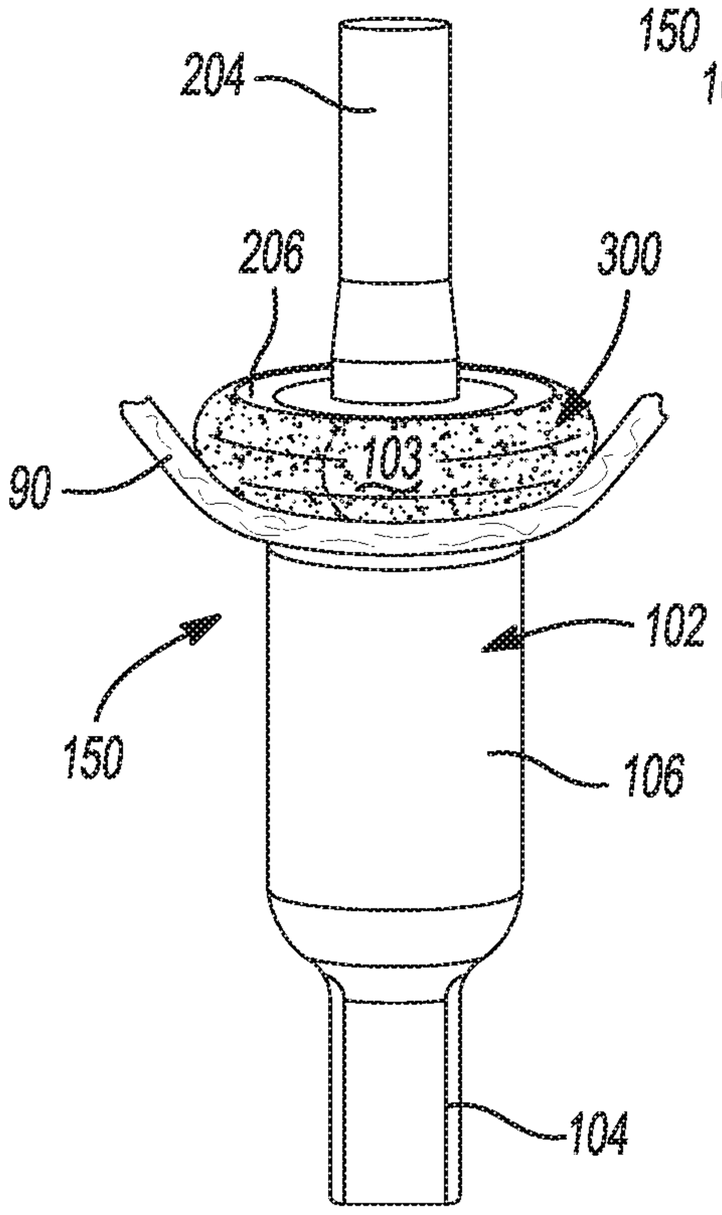
232
206
300D
202
100
108
150
102
106
104

Fig-5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206
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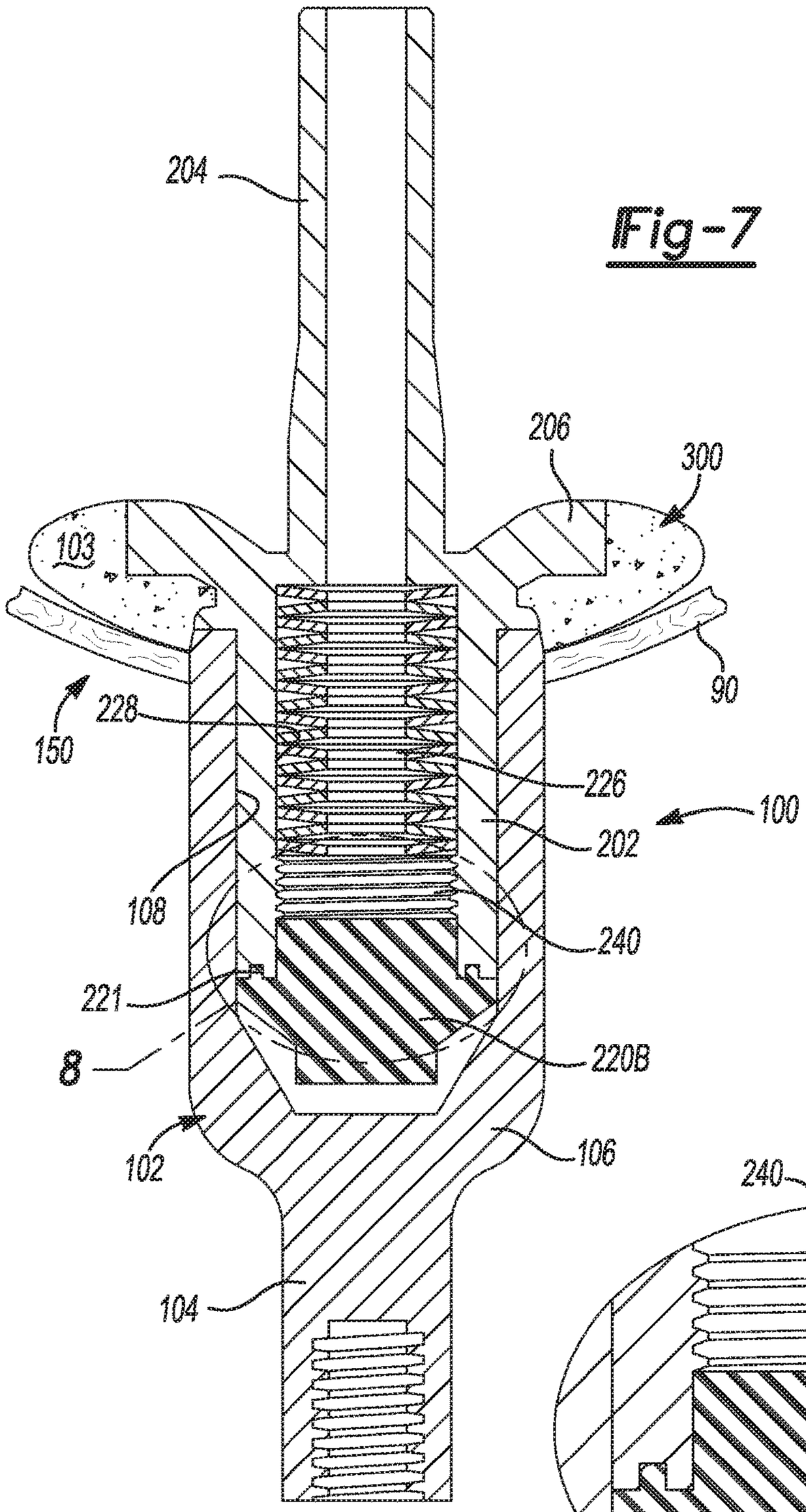
90
103
102
150
106
104

Fig-6


204
206
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103
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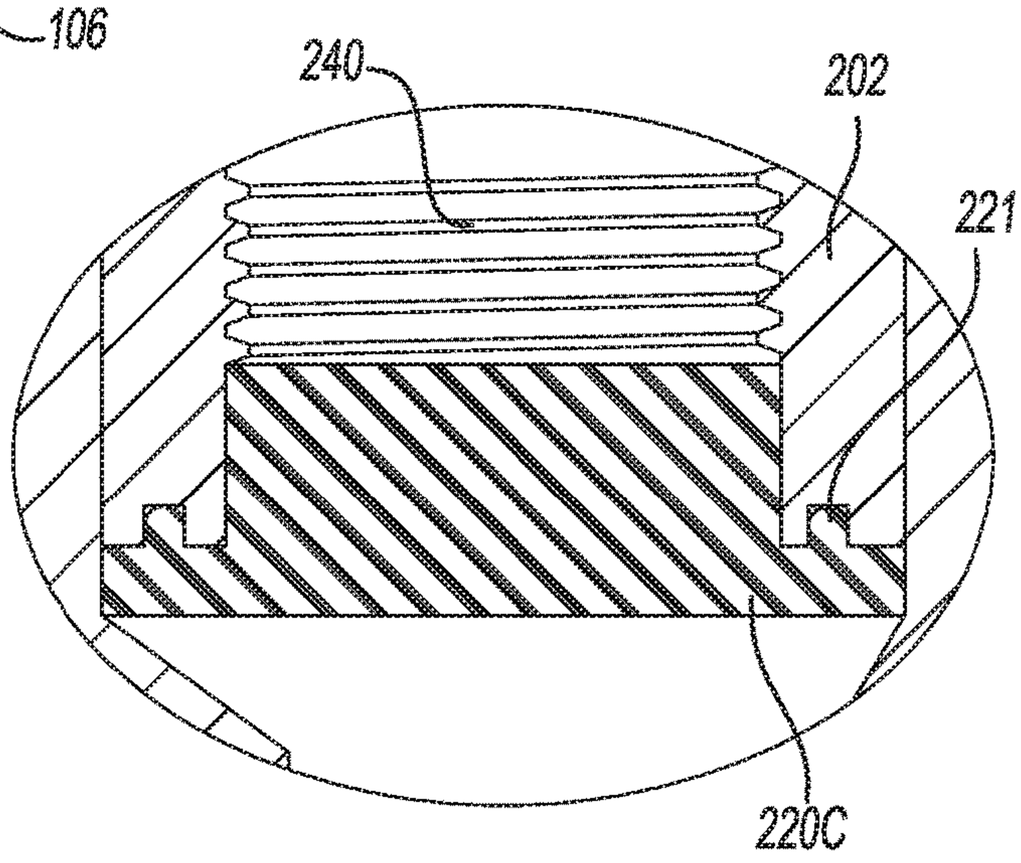
150
228
226
100
202
108
240
221
8
220B
102
106
104

Fig-7

Fig-8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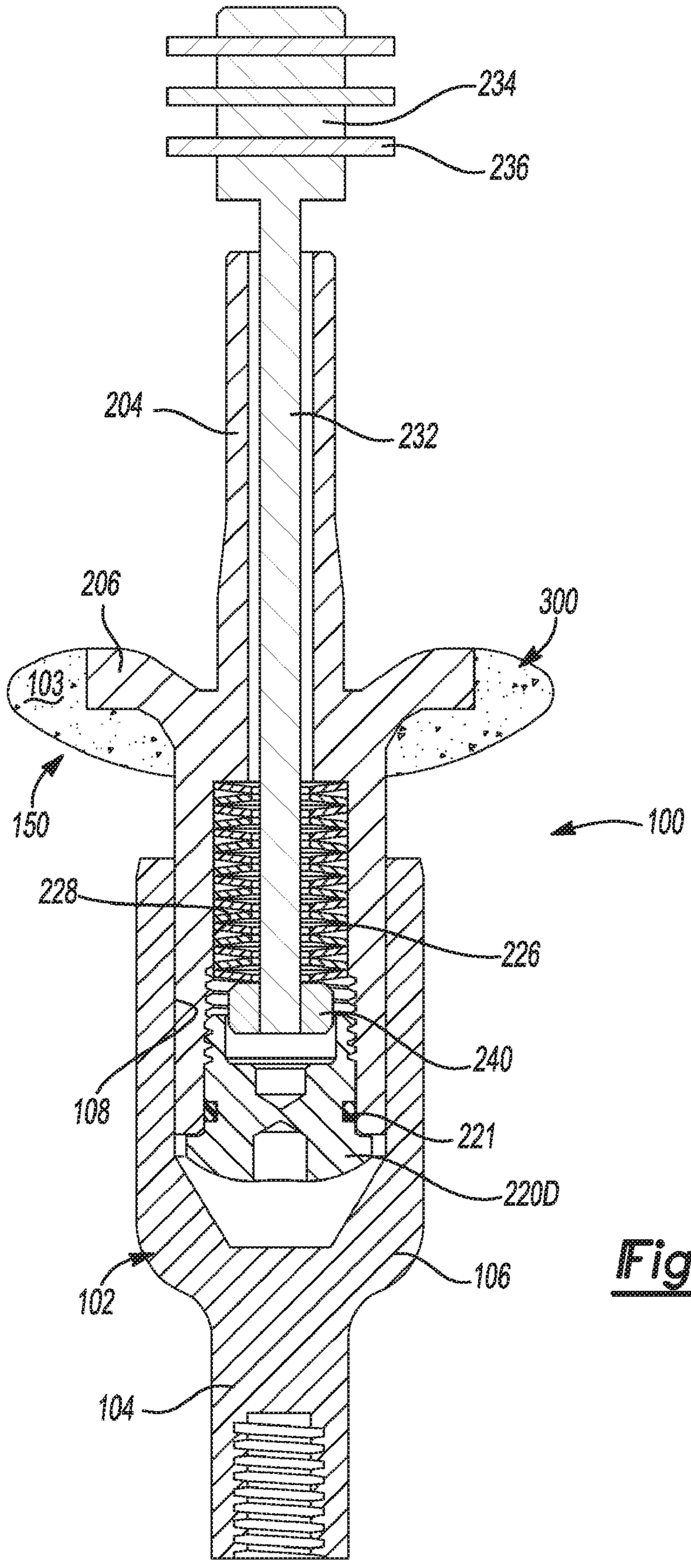
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300
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150
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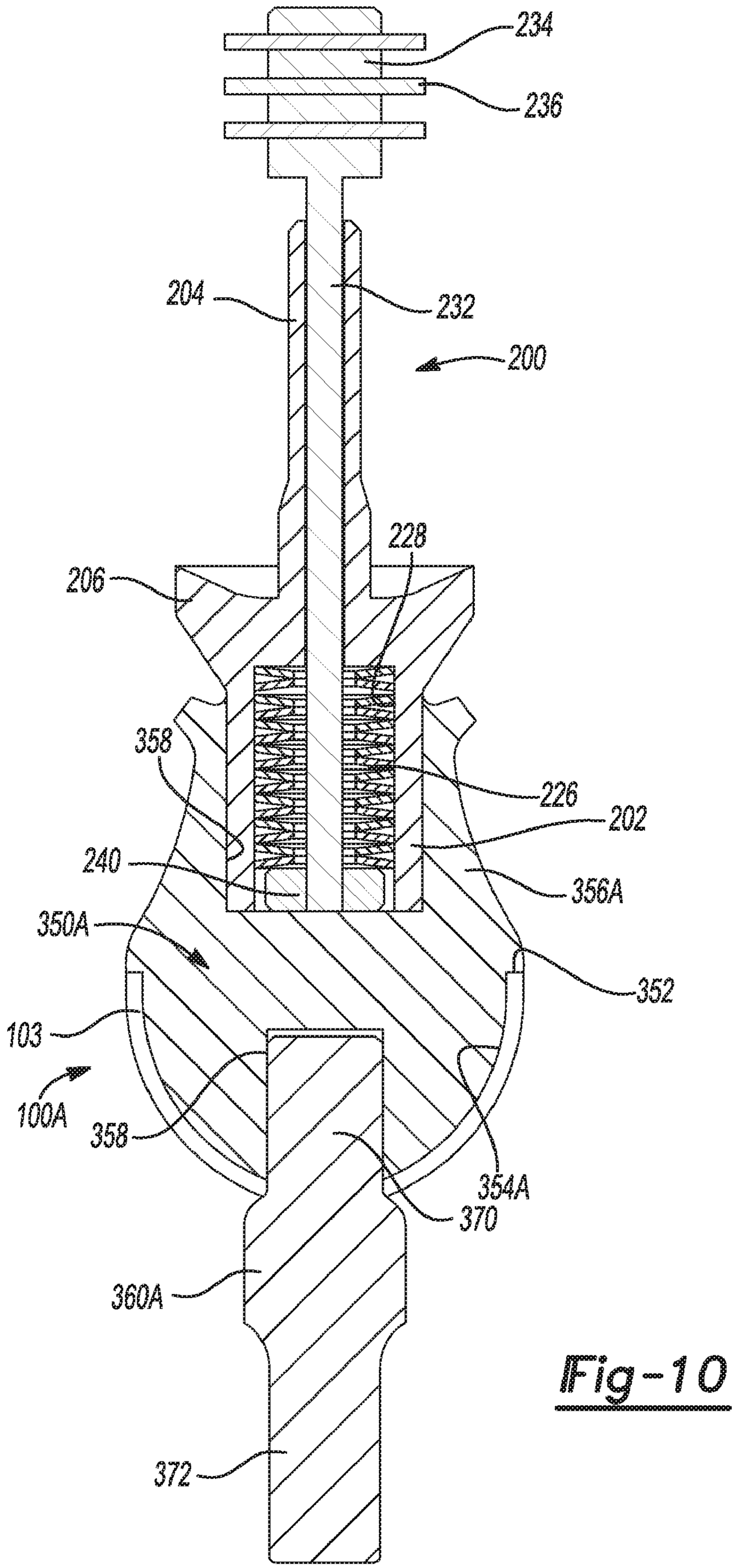
221
220D
106
102
104

Fig -9


234
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204
232
200
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206
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226
202
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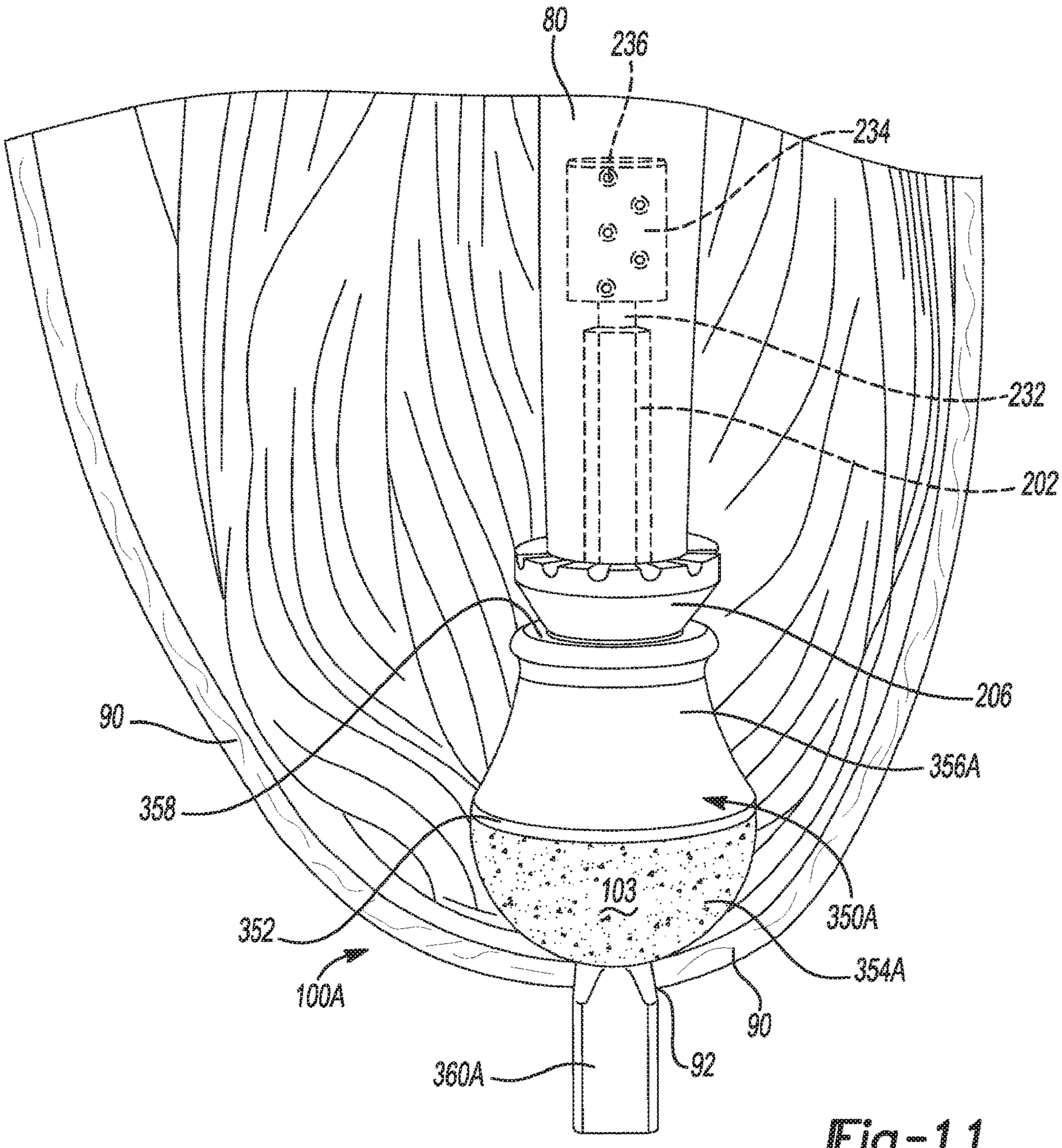
350A
352
103
100A
358
354A
370
360A
372

Fig-10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356A
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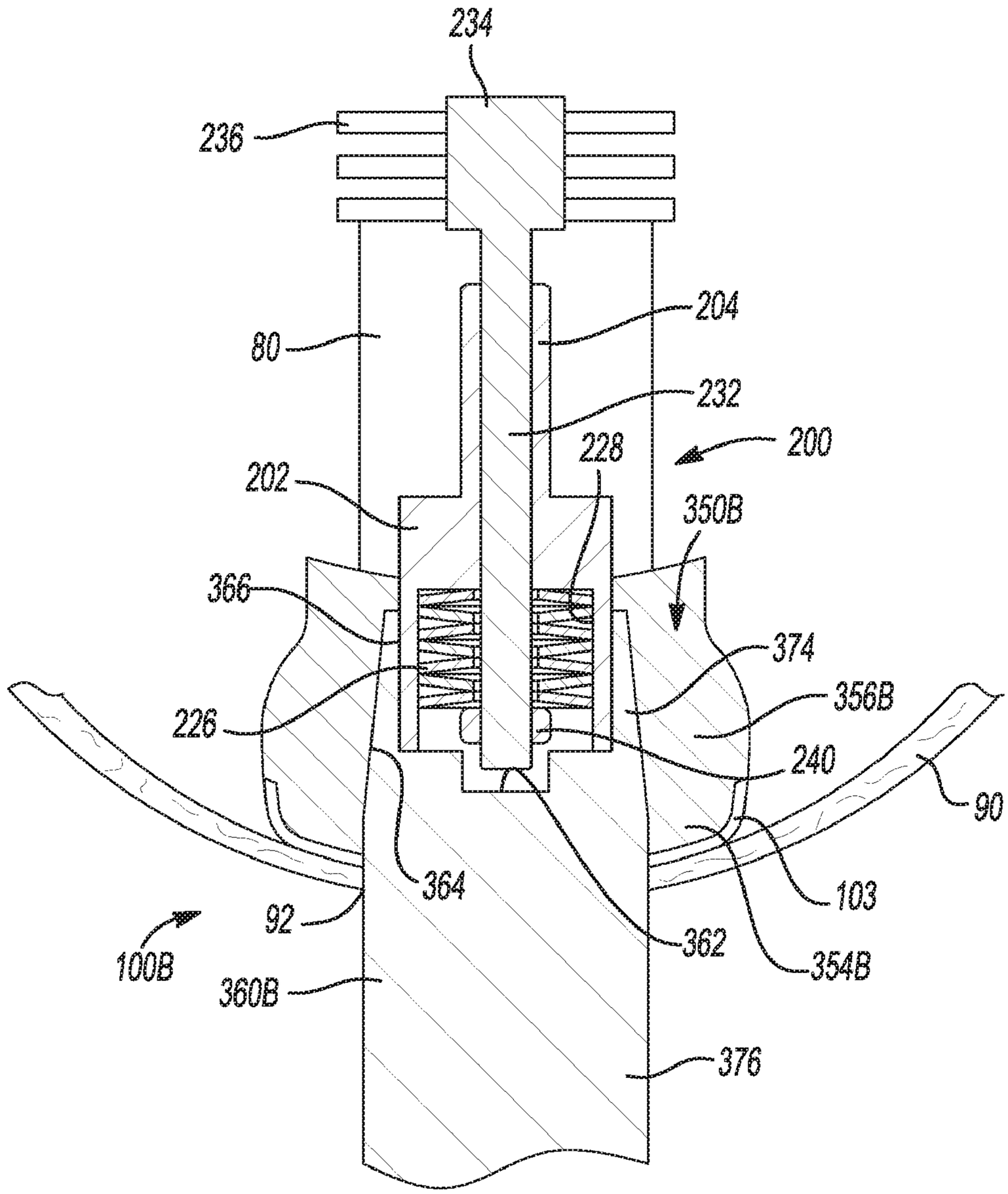
103
352
350A
354A
100A
90
92
360A

Fig-11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204
232
200
228
202
350B
366
374
356B
226
240
90
364
92
103
362
354B
100B
360B
376

Fig-12

TRANSDERMAL INTRAOSSEOUS DEVICE

INTRODUCTION

Various known external fixation devices for amputation or trauma include compliant mechanisms for supporting a prosthetic device to a bone stump. In devices of this type, the compliant fixation mechanism provides a compressive stress at the bone interface for preventing bone resorption over time. Typically, a metal portion of the fixation device may extend beyond the cut surface of the bone, such that soft tissue is attached to the metal, rather than the bone. The interface between the prosthetic device and soft tissue can be a source of infection and various treatments are aimed to reduce it.

SUMMARY

The present teachings provide a transdermal intraosseous device for coupling a bone stump to an external prosthetic device and including a bone fixator, an external connector and a plurality of modular interface components. The bone fixator includes a proximal portion configured for anchoring into the bone stump of the patient and a distal portion including a base collar configured for subcutaneous implantation. The external connector has a distal portion for coupling to the external prosthetic device and a proximal portion for coupling to the distal portion of the bone fixator. Each interface component can be removably coupled to the base collar and has different size and shape to provide a surgeon-selected transition between the prosthetic device and the patient's skin.

The present teachings provide a transdermal intraosseous device for coupling a bone stump to an external prosthetic device and including a bone fixator and a modular transdermal adapter. The bone fixator includes a distal portion and a proximal portion. The proximal portion is configured for anchoring into a bone stump of the patient. The transdermal adapter includes first and second components. The first component has a proximal bore couplable to the distal portion of the bone fixator subcutaneously with a connection. The second component can be removably coupled transcutaneously to the first component.

The present teachings provide a method of implanting a transdermal intraosseous device for coupling an external prosthetic device to a bone stump. The method includes implanting a bone fixator through an intramedullary canal of the bone stump and connecting subcutaneously a first component of a transdermal adapter to a distal portion of the bone fixator. A dome-shaped portion of the first component is covered with skin from the bone stump and the skin is allowed to heal over a porous layer of the dome-shaped portion. A proximal portion of a second component of the transdermal adapter is coupled transcutaneously to the first component.

Further areas of applicability of the present teachings will become apparent from the description provided hereinafter. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

FIG. **1** is an environmental view of a first embodiment of an embodiment of a transdermal intraosseous device for a bone stump according to the present teachings;

FIG. **2** is a sectional view of a transdermal intraosseous device for a bone stump according to the present teachings taken along a longitudinal central axis corresponding to the bone stump axis and illustrating in phantom lines four embodiments of a transdermal adapter of a transdermal intraosseous device, including the embodiment of FIG. **1** and the embodiments of FIGS. **3-5**;

FIG. **3** is an environmental view of a second embodiment of a transdermal intraosseous device according to the present teachings, also shown in FIG. **2**;

FIG. **4** is an environmental view of a third embodiment of a transdermal intraosseous device according to the present teachings, also shown in FIG. **2**;

FIG. **5** is an environmental view of a fourth embodiment of a transdermal intraosseous device according to the present teachings, also shown in FIG. **2**;

FIG. **6** is a sectional view of an embodiment of a transdermal intraosseous device showing a transdermal adapter at a first location relative to the skin the according to the present teachings;

FIG. **7** is a sectional view of an embodiment of a transdermal intraosseous device showing a transdermal adapter at a second location relative to the skin according to the present teachings;

FIG. **8** is an alternative embodiment of a corresponding detail of FIG. **7**;

FIG. **9** is a sectional view of another embodiment of a transdermal intraosseous device according to the present teachings;

FIG. **10** is a sectional view of another embodiment of a transdermal intraosseous device for a two-stage procedure according to the present teachings;

FIG. **11** is an environmental view of transdermal intraosseous device of FIG. **10**; and

FIG. **12** is a sectional view of another embodiment of a transdermal intraosseous device for a two-stage procedure according to the present teachings.

Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

The following description is merely exemplary in nature and is in no way intended to limit the present teachings, applications, or uses. Example embodiments are provided so that this disclosure will be thorough, and will fully convey the scope to those who are skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, and methods, to provide a thorough understanding of embodiments of the present disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that example embodiments may be embodied in many different forms and that neither should be construed to limit the scope of the disclosure. In some example embodiments, well-known processes, well-known device structures, and well-known technologies are not described in detail.

The present teachings can be used for attaching any external prosthetic device to a bone through skin via a transdermal intraosseous device. The transdermal intraosseous device can include a transdermal adapter and an intraosseous fixator. In some embodiments, the intraosseous fixator can optionally include a compliant fixator, such as, for example, the Compress® Pre-Stress Implant, which is

commercially available from Biomet, Inc. Warsaw, Ind. Compliance, as used herein, is a measurement of softness as opposed to stiffness of a material. Compliance of a structural member is generally the reciprocal of Young's modulus (one dimension) or the inverse of the stiffness matrix (more than one dimensions). Accordingly, a compliant member is generally a structural member that has enhanced compliance, such as an elastic spring, bellows, Belleville washers and other elastically biasing members. The compliant fixator of the present teachings, as well as the Compress® Compliant Pre-Stress Implant, allows osseointegration at the bone/implant interface and can provide a stable, high-pressure/implant interface. The compliant fixator can also assist in the prevention of stress shielding and any concomitant bone loss.

Infection is generally a common complication with known transdermal (transcutaneous) intraosseous devices. Aggressive apical epithelial migration or epithelial downgrowth may be initiated as a normal wound-healing response to foreign bodies. If not prevented, this response may result in deep pocket formation and subsequent marsupialization of the transdermal devices. Sub-epithelial connective tissue adhesion to a transdermal intraosseous device may prevent epithelial downgrowth and associated complications, such as infection. Various other surface and/or therapeutic treatments can also be provided at the skin interface, as discussed below.

Referring to FIGS. **1** and **2**, an exemplary transdermal intraosseous device **100** according to the present teachings can include an external connector **102** for connection to an external prosthetic device (not shown), a transdermal adapter **150** at the skin interface area and an intraosseous bone fixator **200** for compliant or non-compliant fixation into an intramedullary bore or IM canal **82** of a bone **80**, such as a femur, tibia, humerus, etc., that is partially amputated (bone stump) and will receive the external prosthetic device. Muscle tissue is indicated at **84** and skin at **90** in FIG. **1**. Accordingly, the bone fixator **200** can be a compliant fixator that can provide pre-stress to the bone or a non-compliant fixator in the form of a static (non-dynamic) anchoring member. The transdermal adapter **150** can include a porous titanium material, such as Regenerex® Porous Titanium Construct, commercially available from Biomet, Inc., Warsaw, Ind. Similarly to Regenerex®, the porous titanium material may have an average porosity of about 67 percent and pore size ranging from about 100 to about 600 microns (average of 300 microns), as well as high strength and flexibility, and could be manufactured using traditional manufacturing methods, or with additive manufacturing.

Additionally, various surface and/or therapeutic treatments can be used to improve the biocompatibility of the transdermal intraosseous device **100** at the skin interface. These treatments include, for example, the use of various anti-microbial technologies, such as silver coating, antibiotic application through surface immobilization or impregnation followed by a controlled release, diamond-like carbon coating, electrochemical processes that change the surface free energy, and highly polished titanium surfaces. Further, various biological technologies can be used to improve dermal integration of the transdermal intraosseous device **100** at the skin interface, such as functionalization of porous metal or polymer with cell adhesive peptides, proteins, macromolecules, monomers, autologous or synthetic chemokines, etc. Skin integration can also be promoted via mechanical immobilization of the skin to an in-growth surface of the transdermal intraosseous device **100** by using soft tissue clamps, sutures, screws, pads, or, alternatively, by allowing relative motion between the transdermal intraosseous device **100** and the skin at their interface. A sliding collar over a rubber or elastomer plug with antibiotic or other antimicrobial agents can used, for example, at the skin/transdermal adapter interface. Such relative motion may reduce tensile load to the healing skin site, and the elastic plug can prevent or reduce friction.

The transdermal adapter **150** can include one or more removably coupled modular interface components (**300**A, **300**B, **300**C, **300**D) as well as portions of the bone fixator **200** shown at **202**, **206** in FIG. **2**. Accordingly, the transdermal adapter, as used herein, refers to those portions of the transdermal intraosseous device (modularly or monolithically attached) that are configured to reside at the interface of the skin with the transdermal intraosseous device **100** and adjacent areas.

As discussed above, the bone fixator **200** can be a compliant fixator configured to provide a bone biasing force to a portion of a bone. Any known compliant fixator can be used, including, but not limited to, the compliant fixators disclosed in commonly assigned U.S. Pat. Nos. 7,722,678, 7,141,073, 6,712,855, 6,508,841 and 6,197,065, all of which are assigned to common assignee Biomet Manufacturing Corp., and are incorporated herein by reference. The compliant fixator **200** is configured to provide a compressive load on the bone, thereby reducing bone loss and promoting bone growth. The compliance of the bone fixator **200** can exceed that of native bone **80**, such that stress shielding does not occur. Additionally, the native bone **80** can experience physiologic dynamic compressive loading biased by a preset spring compression. In this context, evidence of bone hypertrophy or lack of bone loss may occur near the resection level resulting in increased bone strength, possibly as a result of a phenomenon known as Wolf's Law.

An exemplary compliant bone fixator **200** is illustrated in FIG. **2**. The bone fixator **200** can include a distal portion **202**, a proximal portion **204** and an intermediate portion in the form of a skirt-like collar **206** (base collar **206**) between the distal portion **202** and the proximal portion **204**. The distal portion **202** is configured to be coupled to the external connector **102** with any appropriate connection mechanism or portion, such as a taper-to-taper connection or any appropriate removable connection, as discussed below. The proximal portion **204** is an elongated tubular member received into the bore **84** of the bone **80** and is coupled to an anchoring member **230** for anchoring into the bone **80**. The anchoring member **230** can include an elongated shaft **232** and an anchoring plug **234** connected to one end of the shaft **232**. The anchoring plug **234** can be enlarged relative to the shaft **232** and can be fixed to the bone **80** with transverse pins or other bone screws **236**. A portion of the shaft **232** opposite the plug **234** passes through a bore **224** of the proximal portion **204** of the bone fixator **200**. The bore **224** of the proximal portion **204** communicates with an enlarged bore or well **228** formed in the distal portion **202** of the bone fixator **200** and configured to receive the compliant member **226**.

The external connector **102** can include a distal portion **104** for connecting with the prosthetic device and an enlarged tubular proximal portion **106** having an inner bore **108** for taper to taper connection with the distal portion **202** of the bone fixator **200**. The well **228** with the included compliant member **226** are accommodated in the enlarged tubular proximal portion **106** of the external connector **102**.

The compliant member **226** can be include one or more compliant elements, such as one or more Belleville washers, as shown in FIGS. **2** and **7** or other spring washers, or a

single or double helical spring. Detailed descriptions of the structure and operation of various compliant fixators **200** and biasing mechanisms are provided in the above-referenced patents. The well **228** that receives the compliant member **226** is shaped and configured for accommodating the compliant member **226**, such that the well **228** may have a larger diameter for Belleville washers than for a helical spring. The compliant bone fixator **200** can be anchored to the bone **80** and pre-stressed via the anchoring member **230**. The elongated shaft **232** of the anchoring member **230** can have a threaded distal end **238**. The shaft **232** can pass through the longitudinal bore **224** and through the Belleville washers, when Belleville washers are used as the compliant member **226**. Alternatively, the shaft **232** can be integrally attached to the compliant member **226** and be formed as a single monolithic component, when the compliant member **226** is in the form a helical spring. The compliant bone fixator **200** can be inserted through a hole/incision punched through the skin and anchored into the bone **80** via the anchoring member **230**, while the compliant member **226** is held with a temporary tubular knob (not shown). A nut **240** can be threaded on to the distal threaded portion **238** of the shaft **232** and rotated to pre-stress the compliant member **226** to a desired amount. The temporary tubular knob may then be removed and replaced optionally with a sealing plug or cap, such as cap **220**A in FIG. **2**, for example.

The base collar **206** can be either modularly (i.e., removably) or fixedly coupled subcutaneously to the bone fixator **200**. In some embodiments, the base collar **206** or at least the surfaces of the base collar **206** that come into contact with the anatomy of the patient, can be coated with a porous titanium plasma spray with a hydroxyapatite (HAS) coating or other similar treatment for increased biologic fixation. The base collar **206** can be fixed to a resected distal surface of the bone **80** with anti-rotation pins or other fasteners through corresponding apertures. In the embodiments illustrated in FIGS. **1-5**, a plurality of modular interface components designated as **300**A to **300**D and corresponding to FIG. **1** (**300**A), FIG. **3** (**300**B), FIG. **4** (**300**C) and FIG. **5** (**300**D) can be provided to the surgeon as a kit and a surgeon-selected selected interface component can be placed over the base collar **206** and attached thereto. The relative geometry of the modular interface components **300**A-**300**D is illustrated in FIG. **2**, with the outer surfaces of the modular interface components **300**A-**300**D illustrated using different lines. Each of the modular interface components **300**A-**300**D includes two semi-annular portions (right and left side) that can be coupled or snapped on the base collar **206** with any type of connector mechanism or quick connector device or arrangement, such as, for example, dovetail connectors, tongue and groove connectors, taper junction connectors, or screws. Each interface component **300**A to **300**D can be removably coupled to the base collar subcutaneously. Different sizes and shapes are provided for surgeon selection or customized per surgeon's specifications to provide a surgeon-selected transition between the external prosthetic device and the patient's skin **90**.

The external adapter **102** and the bone fixator **200** can be made from a biocompatible metal, such as polished titanium alloy (Ti-6-4). The modular interface components **300**A-**300**D can also be made of titanium alloy or other metal and can be coated with a porous structure or coating **103** to improve biocompatibility at the skin interface. The porous coating or layer **103** may include a porous metal structure, such as the Regenerex® Porous Titanium Construct discussed above. The porous coating **103** can include a roughness treatment formed by blasting, including ceramic bead blasting, sand blasting, grit blasting and similar treatments. Acid etching, such as an Osseotite® treatment can also be used. Osseotite® is a surface treatment commercially available from Biomet, Inc., Warsaw, Ind.

The transdermal intraosseous device **100** can be impacted in position for locking the tapered connection between the external connector **102** and the distal portion **202** of the bone fixator **200**. The skin flap around the incision can be sutured around the external portion of the intraosseous transdermal device **100**.

Referring to FIGS. **1-5**, several modular interface components **300**A to **300**D (or generically **300**) are designed to accommodate optimal contact between the skin and the intraosseous transdermal device **100**. Several modular interface components **300** can be provided to the surgeon or designed specifically for a patient's needs. Some the modular interface components **300** can be designed to be either partially or entirely under the patient's skin **90** and can have different dimensions and shapes as illustrated in FIGS. **1-5**. The size of the surface area and the curvature of the transition at the skin interface varies among the interface components **300**A to **300**D, such that an appropriate interface component can be selected by the surgeon to optimize and improve initial adhesion and limit skin damage respectively for each specific patient. The semi annular or semi-toroidal shapes can include curved portions of different curvature and dimensions and, in some embodiments, planar portions.

Referring to FIG. **5** or **6** and **7**, two versions of the intraosseous transdermal device **100** are compared. In FIG. **5**, the taper connection between the proximal tubular portion **106** of the external connector **102** and the distal portion **202** of the bone fixator **200** terminates outside the skin and outside the porous layer **103** of the interface component **300**. In contrast, in the version of FIG. **7** the taper connection extends under the skin **90** and into the porous layer **103** of the interface component **300**. The geometry of FIG. **7** may provide an additional barrier against infection because the innate immune response could combat potential migration into the taper connection.

Referring to FIGS. **7**, **8** and **9**, another barrier against microbial infiltration can be provided by incorporating a gasket or plug **220**B, **220**C, and **220**D of medical grade elastomer, such as silicone, having an interference fit with the well **228** that houses the compliant member **226**. An O-ring **221** can provide an additional barrier to seal the intramedullary canal **82** of the bone **80**. Three different geometries of the plug **220**B, **2200**, **220**D are illustrated in FIGS. **7**, **8** and **9** (only the relevant detail is shown in FIG. **8**). The silicone O-rings could have multiple placement options. For example, while a single O-ring **221** is illustrated in FIGS. **7-9**, multiple O-rings **221** can be used where placement can exemplary be a combination of that shown in FIGS. **7-9**. In this regard, an O-ring **221** can be positioned in a groove formed in the distal portion **202** of the base fixator **200** as shown in FIGS. **7-8** and/or a groove can be formed as shown in the plug **220**D of FIG. **9** for receipt of O-ring **221**. Alternatively, the placement of the grooves can also be reversed, where the groove is formed directly opposite to the illustrated position for receipt of the O-ring **221**. In other words, the groove can be found in either the plug **220** or the distal portion **202** at the illustrated locations or any other locations.

Referring to FIGS. **10-12**, two versions of a transdermal intraosseous device **100**A, **100**B for a two-stage surgical procedure are illustrated. In these embodiments, the compliant member **226** of the bone fixator **200** is accommodated

subcutaneously, i.e., under the skin **90** of the patient, as discussed below. Corresponding elements of the bone fixator **200** are referenced with the same numerals as in FIGS. **1-9** and their description is not repeated.

Each of the transdermal intraosseous devices **100**A, **100**B includes a corresponding modular transdermal adapter **350**A, **350**B that includes, respectively a first component **356**A, **356**B and a second component **360**A, **360**B removably coupled to one another. The first components **356**A, **356**B are subcutaneous and are implanted during the first stage and coupled to the distal portion **202** of the bone fixator **200** by any appropriate connection mechanism such as by a taper-to-taper connection, as in the embodiments discussed in FIGS. **1-9**. The skin **90** is closed by the surgeon over a porous layer **103** of the first component **356**A, **356**B and allowed to heal and integrate with the porous layer **103**, before the second stage of the surgical procedure. The second components **360**A, **360**B are transcutaneous and coupled to the corresponding first components **356**A, **356**B during the second stage of the procedure, as discussed below. At the second stage, an opening **92** is made in the skin with a scalpel or a biopsy punch and the second component **360**A, **360**B is coupled to the corresponding first component **356**A. **356**B with another taper-to-taper connection or other type of removable connection, such a threaded connection, for example.

More specifically, and referring to FIGS. **10** and **11**, the first component **356**A of the transdermal adapter **350**A includes a dome-shaped portion **354**A that can be partially coated with a coating layer **103** up to a circumference **352** for promoting skin adhesion and biological integration. The first component **356**A has a proximal tapered bore **358** that receives the tapered distal portion **202** of the bone fixator **200**, and a distal tapered bore **358** coupled with a proximal portion **370** of the second component **360**A with a taper-to-taper connection. Other types of removable connections can also be used. The compliant member **226** is received in the bore **228** of the distal portion **202** of the bone fixator **200**, such that the compliant member **226** is accommodated subcutaneously in the appropriately-sized bore **358** of the first component **356**A and in a proximal portion of the transdermal adapter **350**A. A distal portion or external connector **372** of the second component **360**A can be coupled to an external prosthetic device for the bone stump of the patient.

Referring to FIG. **12**, the first component of the **356**B of the transdermal adapter **350**B has a dome-shaped or rounded portion **354**B and is partially coated with a coating layer **103** at the skin interface for promoting skin adhesion and biological integration. The first component **356**B has a distal tapered bore **364** that receives a tapered end of the second component **360**B with a taper-to-taper connection, although other types of removable connections can also be used. The second component **360**B has a tubular proximal portion **374** with a proximal tapered bore **366** that receives the tapered distal portion **202** of the bone fixator **200** and forms a well **362** for the compliant member **26** and nut **240** at the distal portion **202** of the bone fixator **200**. Accordingly, the compliant member **226** is also accommodated subcutaneously in a proximal portion of the transdermal adapter **350**B. A distal portion **376** of the second component **360**B can be coupled to an external prosthetic device for the bone stump of the patient.

Summarizing, the transdermal intraosseous devices of FIGS. **10-12** allow the surgeon to use a two-stage surgical procedure. During the first stage, only the first component (**356**A, **356**B) of the transdermal adapter (**350**A, **350**B) is implanted subcutaneously and coupled to the bone fixator **200**. The skin at the interface (a skin flap of the bone stump) is closed over the porous layer **103** of the subcutaneous first component (**356**A, **356**B). After the wound from the first stage of the surgical procedure has healed, the interfacial skin is punctured to create an opening **92** to couple transcutaneously the second component (**360**A, **360**B) to first component (**356**A, **356**B).

The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

What is claimed is:

1. A transdermal intraosseous device configured for coupling a bone stump of a patient to an external prosthetic device comprising:

a bone fixator comprising:

a distal portion including a tapered portion and a well including a compliant member therein, the distal portion configured to terminate external to skin of the patient;

a proximal portion configured for anchoring into the bone stump of the patient; and

a base collar configured for subcutaneous implantation adjacent to the bone stump;

an external connector comprising:

a proximal portion including a tapered bore configured to receive the tapered portion of the distal portion of the bone fixator to releasably couple the external connector to the bone fixator; and

a distal portion couplable to the external prosthetic device;

a sealing plug disposable in the well and at least partially in the bore of the external connector; and

a modular interface component located proximal of the external component and proximal of the distal portion of the bone fixator, the modular interface component removably coupled to the base collar of the bone fixator.

2. The transdermal intraosseous device of claim **1**, wherein the modular interface component is coated with a porous titanium plasma spray and a hydroxyapatite coating configured to increase biologic fixation.

3. The transdermal intraosseous device of claim **1**, wherein the base collar is configured for fixation to a resected distal surface of the bone stump.

4. The transdermal intraosseous device of claim **3**, wherein the base collar is configured for fixation to the bone stump using anti-rotation pins passing through corresponding apertures of the base collar.

5. The transdermal intraosseous device of claim **1**, wherein the modular interface component is shaped to accommodate optimal contact between the modular interface component and skin of the patient.

6. A transdermal intraosseous device configured for coupling a bone stump of a patient to an external prosthetic device comprising:

a bone fixator comprising:

a distal portion including a tapered portion and a well including a compliant member therein;

a proximal portion configured for anchoring into the bone stump of the patient; and

a base collar configured for subcutaneous implantation adjacent to the bone stump;

an external connector comprising:

a proximal portion including a tapered bore configured to receive the tapered portion of the distal portion of the bone fixator to releasably couple the external connector to the bone fixator; and

a distal portion couplable to the external prosthetic device;

a sealing plug disposable in the well and at least partially in the bore of the external connector; and

a modular interface component removably coupled to the base collar of the bone fixator.

7. The transdermal intraosseous device of claim **6**, wherein the modular interface component is coated with a porous titanium plasma spray and a hydroxyapatite coating configured to increase biologic fixation.

8. The transdermal intraosseous device of claim **6**, wherein the base collar is configured for fixation to a resected distal surface of the bone stump.

9. The transdermal intraosseous device of claim **8**, wherein the base collar is configured for fixation to the bone stump using anti-rotation pins passing through corresponding apertures of the base collar.

10. The transdermal intraosseous device of claim **6**, wherein the modular interface component is shaped to promote contact between the modular interface component and skin of the patient.

11. The transdermal intraosseous device of claim **10**, wherein the modular interface component further comprises two semi-annular portions couplable to the base collar.

12. The transdermal intraosseous device of claim **10**, wherein the modular interface component further comprises two semi-annular portions couplable to the base collar.

13. The transdermal intraosseous device of claim **6**, wherein the modular interface component is configured to be coupled to the base collar using a quick connector device.

14. The transdermal intraosseous device of claim **13**, wherein the quick connector device is selected from the group consisting of a dovetail connector, a tongue and groove connector, and a taper junction connector.

15. The transdermal intraosseous device of claim **14**, wherein the modular interface component is configured to be removably coupled, subcutaneously, to the base collar.

16. The transdermal intraosseous device of claim **6**, wherein the modular interface component is comprised of a titanium alloy coated with a porous structure configured to promote biocompatibility at a skin interface between the modular interface component and skin of the patient.

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